

Ensuring Continued FDA Device Reviews During a Lapse in Appropriations

Without authorizing appropriations legislation, FDA is unable to collect and process new medical device applications and their associated user fees under the Medical Device User Fee Act (MDUFA), which are used to support premarket review activities. While the agency is able to continue these premarket review activities using fees collected before the lapse in appropriations, these funds can quickly be exhausted. In addition, without the ability to process new user fees, a backlog of new product applications can build quickly, delaying patient access to new medical technologies and disrupting medtech companies' business plans. Once the lapse in appropriations is over, FDA is still faced with the task of processing the backlog of applications before its operations can return to normal.

A Legislative Solution to Ensure Continued FDA Reviews and Patient Access to Innovation

AdvaMed is proposing a legislative solution to ensure FDA continues to have access to funds to conduct medical device reviews during a lapse in appropriations.

First, Congress should allow FDA to continue processing new device applications and their associated user fees during a lapse in appropriations. This would ensure the agency's medical device review process continues without interruption and would prevent the creation of any application backlog. Avoiding any such interruption is in the best interests of the agency, medtech companies, and most importantly, American patients.

Second, Congress should authorize FDA to tap into its pool of "unearned" user fees to fund device review activities during a lapse in appropriations. Every year, a number of companies essentially "pre-pay" application or facility registration fees to the agency, and for whatever reason, never submit an application or register a facility. While FDA eventually tries to return these fees or "save" them to pay a company's future fees, these "unearned" fees often just sit in the agency's account, not dedicated to any specific task. These fees accumulate each year and at the end of FY 2017 amounted to \$7.5 million. AdvaMed's proposal would allow the agency to utilize these funds.